

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K041221

B. Purpose for Submission:

New product

C. Analyte:

Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP)

D. Type of Test:

Qualitative immunoassay

E. Applicant:

Accu-Stat Diagnostics

F. Proprietary and Established Names:

Accu-Stat™ Drugs of Abuse Home Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine

G. Regulatory Information:

1. Regulation section:

Unclassified, Test Kit, Multiple Drugs of Abuse, Over the Counter
862.3870, Enzyme Immunoassay, Cannabinoids
862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites
862.3100, Enzyme Immunoassay, Amphetamine
862.3610, Enzyme Immunoassay, Methamphetamine, MDMA (Ecstasy)
862.3650, Enzyme Immunoassay, Opiates
Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

Class II

3. Product Code:

MVO, LDJ, DIO, DKZ, LAF, DJG, and LCM respectively

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

See H.2 below.

2. Indication(s) for use:

“The Accu-Stat™ Drugs of Abuse Home Test Cup for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP) is a single-unit screening test for the rapid detection of two to six of the above drugs in human urine. The designated cut-off concentrations for these drugs are as follows: Marijuana at 50 ng/ml, Cocaine at 300 ng/ml, Amphetamine at 1000 ng/ml, Methamphetamine at 1000 ng/ml, Ecstasy at 500 ng/ml, Opiates at 2000 ng/ml, and Phencyclidine at 25 ng/ml. The tests are intended for over-the-

counter (OTC) consumer use as the first step in a two step process that includes confirmatory testing of preliminary positive results. Information, along with the materials for shipping a portion of the urine specimen to the laboratory is provided.”

3. Special condition for use statement(s):

This device only provides a preliminary analytical test result. A more specific alternative chemical method must be used to obtain confirmed analytical results. Gas chromatography/mass spectroscopy is the preferred confirmatory method but other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test, particularly when preliminary positive results are used.

The assay is for OTC use.

The materials necessary for confirmation testing are provided with the screening device. Materials, as well as confirmation testing, are provided to the consumer at no additional cost. The consumer pays for shipment of the sample to the laboratory.

4. Special instrument Requirements:

Not applicable. This is a visually-read single-use device.

I. Device Description:

The device is a two chamber test cup which is a plastic housing with cap that contains three to five test strips (depending on the number of target drugs) in an isolated chamber. A plastic “key” is used to introduce a portion of the urine into the isolated test chamber to begin the test. The majority of the specimen stays in the main chamber uncontaminated by the test strip reagents and can be used for confirmation testing. The product also includes an instruction booklet, the key described above, a numbered sticker for confidential confirmation testing, a transportation pouch with an absorbent strip, and a pre-addressed mailing box.

J. Substantial Equivalence Information:

1. Predicate device name(s)

Acon Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated E-Z Split Key Cup

2. Predicate K number(s):

K031759

3. Comparison with predicate:

Both devices are identical in product design, performance characteristics, materials, manufacturing, matrix used, and are intended for use as an initial screening method subject to confirmation. The proposed device is intended to be sold over the counter (OTC) while the predicate is for prescription use only.

K. Standard/Guidance Document Referenced (if applicable):

The sponsor did not reference any standards or guidance documents in the pre-market notification.

L. Test Principle:

The device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of antibody-coated particles in the device. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the test line region. The colored line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody. Each strip in the device contains a procedural control that appears in the control line region indicating that the proper volume of urine has been added and membrane wicking has occurred.

M. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:*

The accuracy and precision of the test was demonstrated in a consumer study. 619 unique tests were performed by consumers using drug-free urine that had been spiked with various concentrations and combinations of drugs. Each drug was tested at 0%, 50%, 75%, 125%, 150%, and 200% of the target concentration. Some samples contained as many as three drugs; there were combinations that contained no drugs at all. At least 20 but not more than 43 tests were performed for each combination. Drug concentrations were confirmed by GC/MS; recovery ranged between 78 to 116% of the target concentration. Approximately 11% of the consumers had used a home drug kit before. 98% reported that they were high-school graduates and the ratio of female to male was roughly 1:1. The study took place in four geographic regions, some with several locations, but the settings were not specified.

The results of the study are summarized in the table below:

Drug	Cutoff Concentration (ng/ml)	Number of Studies	Correctly Interpreted	Incorrectly Interpreted*
THC	50	191	189	2
COC	300	190	187	3
AMP	1000	167	165	2
mAMP	1000	183	181	2
MDMA	500	164	162	2
OPI	2000	183	182	1
PCP	25	170	168	2

* All incorrectly interpreted samples, except one, were $\pm 25\%$ of the cutoff value (75% or 125% of target).

A consumer questionnaire was administered to evaluate labeling effectiveness. It asked only one question: “Was the test easy to interpret?” Thus it did not determine whether the labeling adequately alerted users to the limitations of home use testing devices. Only one participant of 619 responded that the test was not easy to interpret.

b. *Linearity/assay reportable range:*

Not applicable for a qualitative assay.

c. *Traceability, Stability, Expected values (controls, calibrators, or method):*

The device has an internal process control. Users are informed that the control indicates that sufficient urine was added to the test. This is typical of OTC tests. Users are also informed not to interpret the test if the control line does not form.

d. *Detection limit:*

Issues were addressed in the predicate submission.

e. *Analytical specificity:*

Issues were addressed in the predicate submission.

f. *Assay cut-off:*

The identified cutoff concentrations are those recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA) for all drugs except MDMA. Analytical performance of the device around the cutoff is described in the precision section above.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Not applicable as the device is only intended for use with urine.

3. Clinical studies:

a. *Clinical sensitivity:*

Not applicable; clinical studies are not typically submitted for this device type.

b. *Clinical specificity:*

Not applicable; clinical studies are not typically submitted for this device type.

c. *Other clinical supportive data (when a and b are not applicable):*

Not applicable; clinical studies are not typically submitted for this device type.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.